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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,965	10/14/2003	E. Neil Lewis	S0001-021002	9949

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EXAMINER	
SUNG, CHRISTINE	

ART UNIT	PAPER NUMBER
2884	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/684,965	LEWIS ET AL.	
	Examiner	Art Unit	
	Christine Sung	2884	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *35-52* is/are allowed.

6)☒ Claim(s) *1,4-15,17-22,24-27 and 30-34* is/are rejected.

7)☒ Claim(s) *2-3,16,23,28-29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 22-55 are objected to because of the following informalities: The claims have been misnumbered, as there are two claims that are designated as claim 22, claim 23 and claim 24. The Examiner treated the claims in order, and the claims are referred to in this action in corrected form. However, applicant should note the changes and officially change the claim order on the record and pay any applicable fees for extra claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4-8, 10-15, 17, 20-22, 24-26 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Folestad (US Pre Grant Publication 2002/0125434 A1).

Regarding claim 1, Folestad discloses a spectral acquisition system (figure 1), comprising:

an exploration subsystem (Figure 1, element 1) operative to expose interior portions of a three-dimensional sample (figure 6, element 14), and a spectral acquisition subsystem (Figure 1,

element 4) operative to acquire images of the interior portions exposed by the exploration subsystem (paragraph [0060]).

Regarding claim 4, Folestad discloses that the exploration subsystem (figure 1m element 1) is operative in the field of view (Figure 2, element 4 and element 1) of the spectral acquisition system (Figure 1, element 4).

Regarding claim 5, Folestad discloses a mechanical link (figure 2), an electrical link (figure 1), and a digital link (figure 1) between the exploration subsystem and the spectral acquisition system.

Regarding claim 6, Folestad discloses a control module operative to control the exploration subsystem and process information from the spectral acquisition system (paragraph [0040]).

Regarding claim 7, Folstad discloses that the spectral acquisition system includes a two-dimensional array detector (figure 7, element 18) and a spectrally selective device.

Regarding claim 8, Folestad discloses that the spectral acquisition subsystem operates in near-infrared or mid-infrared spectral regions (claim 21).

Regarding claim 10, Folestad discloses that the exploration subsystem includes a sample embedding substance or binder, which is an inherent element of a pill/tablet.

Regarding claim 11, Folestad discloses actively processing a sample to expose characteristics of interior portions of the sample (figure 6), and acquiring spectral information from the interior portions of the sample exposed in the step of exposing (claim 19).

Regarding claim 12, Folstad discloses that the steps of actively processing and acquiring are applied to a friable material or a pill (element 14) and further including the step of preparing the friable material to withstand the step of actively processing before the step of actively processing (placing the pill into the rotating wheel (figure 3, element 3) for analysis).

Regarding claim 13, Folstad discloses that the steps of preparing, actively processing, and acquiring are applied to a bulk pharmaceutical material (or a pill, element 14).

Regarding claim 14, Folstad discloses that the steps of preparing, actively processing, and acquiring are applied to a pharmaceutical dosage unit (or a pill, element 14).

Regarding claim 15, Folstad discloses that the steps of preparing, actively processing, and acquiring are applied to a pharmaceutical tablet (or pill, element 14) including at least one active ingredient and one inert ingredient (paragraph [0002] demonstrates that pills are inherently made of an active and inactive ingredient).

Regarding claim 17, Folstad discloses repeating the steps of actively processing and acquiring to create a data set of information about different interior portions of the sample (paragraph [0023], Folstad teaches taking multiple images of the sample).

Regarding claim 20, Folstad discloses the steps of actively processing expose planar interior surfaces (claim 19).

Regarding claim 21, Folstad disclose the step of actively processing and the step of acquiring both take place with the sample in a position constrained in at least one dimension (figure 6).

Regarding claim 22, Folstad discloses that the step of actively processing and the step of acquiring both take place as part of an automated sequence (claim 18).

Regarding claim 24, Folstad discloses that the step of acquiring operates in near-infrared or mid-infrared spectral regions (claim 21).

Regarding claim 25, Folstad discloses spectral acquisition system, comprising: means for holding a friable pharmaceutical tablet (Figure 3, element 3), means for exposing interior portions of the friable pharmaceutical tablet, and means for obtaining spectral images of the exposed interior portions (paragraph [0025], Folstad teaches taking multiple images of the sample).

Regarding claim 26, Folstad discloses a means for holding which includes a means for embedding the pharmaceutical tablet (figure 3, element 3).

Regarding claim 30, Folstad discloses a means for holding are operative to hold the pharmaceutical tablet in a field of view (figure 3, element 3) of the means for obtaining spectral images during operation of the means for exposing (figure 2, element 4).

Regarding claim 31, Folstad discloses a mechanical link (figure 2), an electrical link (figure 1), and a digital link (figure 1) between the means for exposing and the means for obtaining spectral images (figure 1).

Regarding claim 32, Folstad discloses a means for controlling the means for exposing and for processing information from the means for obtaining spectral images (paragraph [0040]).

Regarding claim 33, Folstad discloses a means for obtaining spectral images operate in near-infrared or mid-infrared spectral regions (claim 21).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 9, 18-19, 27 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Folstad (US Pre Grant Publication 2002/0125434).

Regarding claims 9 and 34, Folstad does not explicitly state that a vent or airborne waste collection system is connected to the apparatus or system as disclosed in claims 9 and 34. However, Folstad discloses that his invention is directed to on-line tablet detection (paragraph [0009]). One of ordinary skill in the art would be motivated to include a vent with the invention as disclosed by Folstad in order to reduce detector contamination.

Regarding claims 18-19, Folstad does not explicitly disclose a step of selecting a spatial separation between the steps of actively processing to be on the same order as that of a spatial resolution of the step of acquiring. However, when taking multiple images, as disclosed by Folstad, (paragraph [0025]), it would be obvious to one having ordinary skill in the art at the time the invention was made to have such images of the same resolution so that when the images are processed it does not create discrepancies or additional error in the image processing.

Regarding claim 27, Folstad discloses the limitations set forth in claim 27, but does not explicitly specify that there is a holding wax to hold the pill in place. However, Folstad uses a gripping device (figure 6) to secure the pill during detection. One of ordinary skill in the art would be motivated to apply a wax to the gripping device as disclosed by Folstad in order to decrease damage to the pill during detection and to securely grasp the pill during detection.

Allowable Subject Matter

7. Claims 35-52 are allowed.

8. Claims 2-3, 16, 23 and 28-29 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter:

Regarding independent claim 35, none of the prior art of record specifies or makes obvious an acquisition method where a pharmaceutical tablet is analyzed by removing material from the tablet and images are taken after a portion of the tablet has been removed. References such as Folstad disclose spectral imaging of tablets, but do not explicitly specify removal of a

portion of the tablet as conventional references teach using non-destructive mode for analyzing pills or pharmaceutical tablets.

Claims 36-52 are allowable for at least the same reasons disclosed above, as they are dependent on the aforementioned independent claim.

Regarding claims 2-3 and 28-29, none of the prior art of record specifies a spectral acquisition system or apparatus with a cutting implement and guide. A conventional tablet or pill spectral imaging system and/or apparatus detect the pill using non-destructive means (see Folstad for example), because such systems would like the ability to use/sell the tablet after detection. Further although references such as Lindquist (SE 9402033A) discloses a microtome for slicing tablets, it does not disclose the integrated system as claimed, where the tablet is cut and imaged in the same apparatus/system.

Regarding claim 16, none of the prior are of record discloses or makes obvious a spectral acquisition method, namely the step of actively cutting the friable sample. A conventional tablet or pill spectral imaging method detects the pill using non-destructive means (see Folstad for example), because such methods would like the ability to use/sell the tablet after detection. Further although references such as Lindquist (SE 9402033A) discloses a microtome for slicing tablets, it does not disclose the integrated method as claimed, where the tablet is cut and imaged in the same apparatus/system.

Regarding claim 23, none of the prior art of record specifies or makes obvious processing the spectral information acquired in the step of acquiring to obtain two-dimensional chemical image planes and reconstructing at least one three-dimensional image from the two dimensional chemical image planes. Although it is known to use two-dimensional images to construct a 3-D

image (i.e. Computed tomography), none of the prior art of record specifies the claimed step of obtaining 2-d chemical images planes to make a 3-d chemical image plane. References such as Folstad disclose some of the limitations, but do not specify processing to construct a 3-d chemical image from the 2-d images.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Sung whose telephone number is 571-272-2448. The examiner can normally be reached on Monday- Friday 7-3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christine Sung
Examiner
Art Unit 2884

OTILIA GABOR
PRIMARY EXAMINER

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